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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,935	03/06/2002	Adi Shefer	4686-110 US	7056

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/091,935	SHEFER ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-15,17-33,35,36,41,42 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-15,17-33,35,36,41,42 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 07/31/2008.

Claims 2-6, 16, 34, 37-40 and 43-46 have been canceled.

Claims 1, 7-15, 17-33, 35, 36, 41, 42, and 47-49 are pending and included in the prosecution.

The following rejections have been overcome by virtue of applicants' amendment and remarks:

The rejection of claims 1, 7-32, 41, 47-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The rejection of claims 1, 7-32, 35, 36, 41, 47-49 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 33, 42 and rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 42 as previously amended by amendment filed 11/02/2007 recited that "the patch is substantially water-free", which introduced new matter. Recourse to the specification, nowhere applicants disclosed such a limitation. In page 15, lines 27-30, applicants disclosed that method of making the patch comprising the step of dissolving the components in a solvent including water.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 33, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" recited by claims 1, 33, 35, 42, and 48 is a relative term which renders the claim indefinite. The term is not defined by the claim, and the specification does not provide a standard for ascertaining the

requisite degree, and one of ordinary skill in the art would not be reasonably recognize of the scope of the invention.

Response to Arguments

5. Applicant's arguments filed 07/31/2008 have been fully considered but they are not persuasive. Applicants argue that the rejections under 112 first and second paragraphs are obviated by applicants' amendment, however, the amendment made to claims 33 and 42 did not remove the limitation of "patch being substantially water free", therefore rejection of these two claims under 35 U.S.C. 112, first paragraph and under 35 U.S.C. 112, second paragraph are maintained for reasons of record.

The following new grounds of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 13-15, 17, 18, 21, 27, 29-33, 42, 47, 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,780,047 ('047) in view of US 5,667,798 ('798) and US 5,695,779 ('779).

The present claims 1 and 42 are directed to polymeric layer of film forming polymer selected from the group consisting of: maltodextrin, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof, and microencapsulated active agent by spray-drying. Claims 33, 35 and 48 are directed to method of using the polymeric layer.

US '047 teaches patch comprises water-soluble adhesive sheet that can be applied to the skin and have adhesiveness such that if falls off from the skin upon wetting (abstract; col.2, lines 62-64; col.11, lines 13-15). The water-soluble polymers included polyvinyl pyrrolidone and pullulan, i.e. modified starch (col.3, lines 5-8). The adhesive sheet material further comprises glycerol and propylene glycol claimed by applicants in claim 21 as solubilizers (col.5, lines 4-12). The patch of polymer sheet further comprises active agents including drugs, vitamins, lanolin (moisturizer claimed

by claims 14 and 15), vitamins, antiseptic, anti-inflammatory agent, sodium salicylate, amino acids, menthol and capsaicin (col.6, lines 59-64; col.7, lines 61-63; col.8, lines 7-10, 22; col.10, line 25). The adhesive sheet comprises fats and oils that read on permeation enhancer claimed by claim 17 (col.7, lines 38-52). The thickness of the water-soluble adhesive sheet is preferably from 20-1,000 μm, i.e. 0.02 to 1 mm as claimed by claim 29 (col.5, lines 29-33). The active ingredients are uniformly distributed throughout the matrix as implied by the reference disclosure that the ingredients and the polymer matrix are mixed together (col.11, line 65). The reference disclosed amount of water in the water-soluble sheet as low as 0.1% (col.4, lines 66-67). Since the relative term "substantially water free" as instantly claimed was given no explicit definition, the interpretation of the term meets the amount “0.1% of water" disclosed by US ‘047.

US ‘047, however, does not teach microencapsulation of the active ingredients as claimed by claims or the material of the capsules, and does not teach encapsulation is achieved by spray-drying as claimed by claims 1, 33, 35, 42, and 48.

US ‘798 teaches transdermal device comprises matrix comprising active agent dispersed in microencapsulated form to control the release of the active agents (abstract; col.1, line 67-col.2, line 2). The drug release into the matrix is controlled by selecting the microcapsules as hydrophilic or hydrophobic (col.2, lines 9-15).

US ‘779 teaches a released control transdermal therapeutic system achieved by microencapsulating the active agent using spray drying technique (abstract; col.2, lines 29-32; col.7, lines 57-59; col.8, lines 20-25, 39-42)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047, and further microencapsulate the active agent in hydrophobic material as disclosed by US '798, motivated by the teaching of US '798 that microcapsules and their material play role in controlling the release of the active agent, and further uses the spray-drying technique to encapsulate the active agent as taught by US '779 because US '779 teaches that spay drying microencapsulation is preferred technique and provides controlled release of encapsulated drugs from the transdermal device, with reasonable expectation of having topical film of water soluble polymer comprising spray-dried microencapsulated active agents to be delivered to the skin in a controlled release manner effectively according to the intended use.

9. Claims 7, 8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 combined with US '798 and US '779, and further in view of US 2003/0027833 ('833).

The combined teachings of US '047, US '798 and US '779 are discussed in section 8 as set forth in this office action.

Although US '047 teaches active agent in the polymeric film, however, US '047 does not explicitly teach the specific antiseptics claimed by claims 7 and 10 and specific antibiotics claimed by claim 8.

US '833 discloses pharmaceutical composition in the form of single adhesive polymeric layer, film or matrix that deliver local anesthetic agent to the skin (abstract; page 2, paragraphs 0014-0017; page 9, paragraph 0091). The polymeric layer is water-soluble and can be removed easily by application of water, and selected from PVP, PVA, hydroxypropyl cellulose, starch and starch derivatives with a pharmaceutically active agent homogenously admixed therein with a permeation enhancer (page 2, paragraphs 0021, 0023; page 6, paragraph 0070, 71; page 7, paragraphs 0077, 0078). The polymeric layer further comprising additional active agent with the preferred additional active agents including bactericidal agent selected from iodine, silver, mercury compounds, phenol and chlorhexidine (page 4, paragraph 0051) and antibiotic including tetracycline (page 4, paragraph 0052).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver spray-dried microencapsulated active agents to the skin including antiseptic as disclosed by the combined teachings of US '047, US '798 and US '779, and select the antiseptic from iodine, silver, mercury compounds, phenol, chlorhexidine, and/or antibiotic including tetracycline as disclosed by US '833, motivated by the teaching of US '833 that such antiseptics and antibiotics are suitable to be delivered through the skin and are preferred antibiotics and antiseptic to be included in the matrices applied to the skin, with reasonable expectation of having topical film of water soluble polymer to deliver spray-dried microencapsulated active agents to the skin including iodine, silver, mercury compounds, phenol, chlorhexidine, and/or tetracycline that delivers such ingredients to

skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

10. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '047, US '798 and US '779.

The combined teachings of US '047, US '798 and US '779 are discussed in section 8 as set forth in this office action.

Although US '047 teaches anti-inflammatory drugs, however, the reference does not explicitly teach the specific anti-inflammatory ibuprofen as claimed in claim 11.

It is within the skill in the art to determine the species of anti-inflammatory agent to be delivered to the skin by the water soluble polymer film disclosed by the references according to the specific patient need and intended use, since both US '047 disclosed anti-inflammatory agent are suitable for delivery from such films. Applicants failed to show superior and unexpected results obtained by using the water-soluble film to deliver ibuprofen in particular. Therefore, ibuprofen claimed by claim 11 does not impart patentability to the claims, absent evidence to the contrary.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '047, US '798 and US '779 and further in view of US 6,497,887 ('887).

The combined teachings of US '047, US '798 and US '779 are discussed in section 8 as set forth in this office action.

Although US '047 teaches many active agents to be delivered to the skin, however, the references does not explicitly teach antihistamine as claimed in claim 12.

US '887 teaches polymeric membrane in form of matrix dissolvable upon wetting and can be used to deliver biologically active agents to the skin (abstract; col.3, line 45). The membrane permits sustained delivery of active ingredients to the skin and does not have to be peeled or washed off the skin, but simply dissolve (col.6, lines 11-16). The membrane is made of water-soluble polymers such as starches (col.1, lines 60-67; col.2, lines 21-34). The membrane further comprises additional film forming polymers such as hydroxypropyl cellulose and polyvinyl pyrrolidone and polyvinyl alcohols (col.3, lines 18-30). The active agents included in the membrane include moisturizers, salicylic acid, vitamins, whitening agents, antiseptics, anti-inflammatory agents, antihistamine, anti-aging agents, tanning agents (col.5, lines 10-20, 23-25, 33-40, 44, 59-67; col.6, lines 1-4). The membrane further comprises glycerin, that reads on solubilizers and permeation enhancers, and amino acids, that reads on claim 47 (col.3, lines 9-12). The membrane comprises polyphenols, i.e. antiseptic (col.6, line 26). The membrane may be wetted before use or applied to wetted skin (col.4, lines 63-67). The membrane has a thickness 0.1 to 1.5 mm and its shape and size are varied according to the intended use (col.3, lines 50-56). The active ingredients are inherently uniformly distributed throughout the matrix as implied by the reference disclosure that the ingredients and the polymer matrix are mixed together (col.6, line 47).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver spray-

dried microencapsulated active agents to the skin as disclosed by US '047 combined with US '798 and US '779, and replace the active agent by antihistamine as disclosed by US '887, motivated by the teaching of US '887 that such antihistamine can be delivered to the skin by dissolvable film, with reasonable expectation of having topical film of water soluble polymer comprising spray-dried microencapsulated antihistamine to be delivered to the skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the already compromised skin.

12. Claims 9, 19, 20, 22-24, 26, 35, 36, 41, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 combined with US '798 and US '779 and further in view of US 2001/0007671 ('671).

The combined teachings of US '047, US '798 and US '779 are discussed in section 8 as set forth in this office action.

However US '047 does not explicitly teach the salicylic acid as claimed in claim 9, the transparent polymeric film as claimed in claim 19 or colored as claimed in claim 20, the cosmetics claimed in claims 22-24, the effervescent claimed in claim 26, or the period of applying the film as claimed 35, and 36.

US '671 teaches a cosmetic, pharmaceutical, or dermatological patch for application of active agent to the skin (abstract; page 1, 0012, 0015). The patch imparts great softness, freshness and coolness and easily manipulated during application and removal from the skin (page 1, paragraph 0007). The patch includes a water-polymer

matrix layer comprising an active agent and polymer (Figures 1; page 2, 0017, 0018, 0024, 0035; page 3, 0046; page 7, claim 15; page 8, claims 67-70). The active agents include moisturizers, bleaching agents (depigmentation agents), anti-acne agents, anti-aging agents, anti-wrinkle agents, anti-inflammatory agents, softeners, keratolytic agents, etc. (page 3, 0046, 0047). The patch is transparent or colored (page 2, 0020; page 3, 0050). The composition includes acetylsalicylic acid (aspirin) (page 3, 0047). The composition comprises sodium carbonate and sodium bicarbonate (page 3, 0043). The patch is applied to the skin from about few seconds to about few days (page 1, 0015). The composition further comprises salicylic acid, which is a keratolytic agent (page 3, 0048; page 8, claim 60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver spray-dried microencapsulated active agents to the skin as disclosed by US '047 combined with US '798 and US '779, and add effervescent material and select the active agent suitable for delivery to the skin or across the skin according to the specific condition to be treated, and made the film colored or transparent and adjust the time of application of the film as disclosed by US '671, motivated by the teaching of US '671 that such ingredients when applied topically impart great softness, freshness and coolness to the skin, with reasonable expectation of delivering wide varieties of spay dried microencapsulated beneficial active agent to the skin from colored of transparent film for the desired period of time wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

13. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 combined with US '798 and US '779 and further in view of US 6,419,935 ('935).

The combined teachings of US '047, US '798 and US '779 are discussed in section 8 as set forth in this office action.

Although US '047 teaches many active agent delivered from soluble film, however, the reference does not explicitly teach dihydroxyacetone claimed by claim 25, and further does not teach the size of the film as claimed by claim 28.

US '935 teaches cosmetic skin treatment method includes providing a patch with good adhesiveness without drying the skin that includes polymeric matrix that includes at least one cosmetically active compound (abstract; col.1, lines 43-57; col.2, lines 49-57; col.9, lines 66-67). The patch is configured to adhere to the dry skin and to the moistened skin to provide treatment and cleansing the skin (abstract; col.2, lines 1-3, 57-59; col.3, lines 12-14). The patch provides treatment for time ranging from 5 minutes to 60 minutes (col.2, lines 8-12; col.4, lines 64-67). The cosmetically active compounds to be incorporated in the matrix include dihydroxyacetone (col.5, lines 62-65). The patches are cut to shapes designed to fit on various parts of the body and the preferred size ranges from 1 cm^2 to 30 cm^2 (col.9, lines 6-18). The polymeric matrix forms a layer having a thickness of 0.2 mm (col.9, lines 66-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver spray-

dried microencapsulated active agents to the skin as disclosed by US '047 combined with US '798 and Us '779, and use the film to deliver dihydroxyacetone to the skin, and select the specific size of the film according to the area to be treated as disclosed by US '935, motivated by the teaching of US '935 that dihydroxyacetone is a tanning agent suitable for topical delivery from films and such a size of patch is suitable size, with reasonable expectation of delivering spray-dried microencapsulated dihydroxyacetone to the skin from a film that dissolves afterward without the need of the pain of peeling off of the film from the skin.

Response to Arguments

14. Applicant's arguments filed 07/31/2008 have been fully considered but they are not persuasive. The main gist of applicants' argument against the U.S.C. 103 rejections set forth in this office action is that the references do not teach spray dried microcapsules.

In response to this argument, it is argued that spray-dried technique for making microcapsules is known in the art, and is taught by the newly cited reference US '779 used in the rejection as set forth in this office action. US '779 teaches spray-dried microcapsules used in transdermal devices and provide controlled release of the encapsulated agents. In any events, the limitation of "spray-dried" is directed to method of making the claimed product, and does snot impart patentability to claims directed to product and method of its use.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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